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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,424	04/02/2007	John G. Babish	068911-0160	7031

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EXAMINER	
CARTER, KENDRA D	
ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
06/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mweipdocket@mwe.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,424	BABISH ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,17 and 21-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,17 and 21-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/23/10;6/17/09;3/10/09;7/3/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II, claims 16-32 in the reply filed on March 23, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election with traverse of reduced isoalpha acids and curcumin in the reply filed on March 23, 2010 is acknowledged. The traversal is on the ground(s) that the compounds are structurally and functionally similar. This is found persuasive and thus the species election of the isoalpha acid and curcuminoid is withdrawn.

The requirement of the group restriction is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 16, 17, 21, 22, 25 and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Babish et al. (US 2003/0096027 A1).

The applied reference has a common inventor (John G Babish) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Babish et al. teach a formulation to inhibit inflammatory response in animals comprising curcumin and alpha acid or beta acid derivatives such as isohumuone, dihydroisohumulone and tetrahydroisohumulone (see claims 1, 2, 4, 10 and 17; addresses claims 16, 17, 21, 22 and 32). The composition comprises about 0.025 to about 1 wt% of the hops extract (see claim 20; addresses claim 29). The composition

comprises a pharmaceutical carrier and can be applied topically, orally, parenterally, transdermally and transmucosally (see claims 14 and 19; addresses claim 30 and 31). The ratio between the fraction of hops and the curcuminoid can range from 10:1 and 1:10 (see table 6). The amount of the fraction isolated from hops can be between about 0.5 to about 20 mg/kg (see paragraph 51).

2) Claims 16, 17, 22, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Newmark et al. (US 6,391,346 B1).

Newmark et al. teach a oral composition comprising 7% (7 mg) curcumin, 35% (17 mg) of humulones, 12% (6 mg) of lupulones (i.e beta acid), and 1.5% (0.37mg) of xanthohumol in a pharmaceutical carrier (see column 7, lines 1-3 and table; addresses claims 16, 17, 22, 30 and 31). The composition preferably contain the supercritical carbon dioxide extract of hops (see column 6, lines 5-10). The hydroalcoholic extract of hops is from about 1% to about 2% (see column 6, lines 32-34).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 23, 24 and 26-29 are rejected under 35 U.S.C. 103(a) as being obvious over Babish et al. (US 2003/0096027 A1).

The applied reference has a common inventor (John Babish) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application

and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teaching of Babish et al. is as applied in claims 16, 17, 21, 22, 25 and 29-32 above.

Babish et al. does not teach the specific ranges of the fraction isolated from hops (claims 26-28), or the ratio between the fraction derived from hops and the curcumionoid (claims 23 and 24).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the compositions and methods of Babish et al. and the specific ranges and ratios claimed in claims 23, 24 and 26-28 because Babish et al. teach the amounts and ranges that are within the range of range claimed. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Particularly, Babish et al. teach the following: 1) the ratio between the fraction of hops and the curcuminoid can range from 10:1 and 1:10 (see table 6); 2) the amount of the fraction isolated from hops

can be between about 0.5 to about 20 mg/kg (see paragraph 51); and 3) the composition comprises about 0.025 to about 1 wt% of the hops extract (see claim 20).

2) Claims 21 and 23-29 are rejected under 35 U.S.C. 103(a) as being obvious over Newmark et al. (US 6,391,346 B1) as applied to claims 16, 22, 30 and 31 above, in view of Klusters (US 4,758,445).

The teachings of Newmark et al. are as applied to claims 22, 30 and 31 above.

Newmark et al. does not teach isoalpha acids (claim 25) or the specific compounds of claim 21. Newmark also does not teach the specific ranges of the fraction isolated from hops (claims 26-29), or the ratio between the fraction derived from hops and the curcumionoid (claims 23 and 24).

Klusters et al. teach that hop extracts obtained by extracting hops with supercritical carbon dioxide contains iso-alpha acids such as trans-isohumulone.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the composition of Newmark et al. and isoalpha acids or the specific compounds of claim 21 because the composition of Newmark et al. comprises a supercritical carbon dioxide extract of hops, and Klusters et al. teach that

the supercritical carbon dioxide extract of hops comprises iso-alpha acids such as trans-isohumulone.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the composition of Newmark et al. and the specific ranges and ratios claimed in claims 23, 24 and 26-29 because Newmark et al. teach the amounts and ranges that are within the range of range claimed. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Particularly, Newmark et al. teach the following: 1) a oral composition comprising 7% (7 mg) curcumin, 35% (17 mg) of humulones, 12% (6 mg) of lupulones (i.e beta acid), and 1.5% (0.37mg) of xanthohumol in a pharmaceutical carrier (see column 7, lines 1-3 and table); and 2) a composition comprising from about 1% to about 2% supercritical carbon dioxide extract of hops (see column 6, lines 5-10 and lines 32-34).

3) Claims 1 and 32 is rejected under 35 U.S.C. 103(a) as being obvious over Heng (WO 00/70949 A1), in view of Beiersdorf (WO 03/003997 A3).

Heng teach a composition and method comprising curcumin and an anti-inflammatory drug to treat inflammatory disease (see title and abstract).

Heng does not teach a fraction derived from hops.

Beiersdorf teach that hop extracts are used to treat inflammatory conditions (see abstract).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the composition and method of Heng and an extract of hops because Heng teaches that the anti-inflammatory composition can comprise and additional anti-inflammatory agent, and Beiersdorf teach that extracts of hops treats inflammatory conditions. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kendra D Carter/
Examiner, Art Unit 1627

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627